OCT 19 2009

APPENDIX I

510(K) Summary

510(k) Summary

SUBMITTER:

Sorin Group Italia S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

Luigi Vecchi
Phone: 39 0535 29811
Fax: 39 0535 25229

DATE PREPARED:

September 18, 2009

DEVICE TRADE NAME:

APEX HP M Adult Hollow Fiber Membrane Oxygenator

COMMON NAME:

Hollow Fiber Oxygenator

CLASSIFICATION NAME:

Cardiopulmonary Bypass Oxygenator

LEGALLY UNMODIFIED DEVICE:

APEX HP M. Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator (#K083021)

PREDICATE DEVICE:

APEX M Adult Hollow Fiber Membrane Oxygenator (#K014080)

DEVICE DESCRIPTION:

The Apex HP M Adult Hollow Fiber Membrane Oxygenator is a cardiopulmonary bypass blood oxygenator with an integral heat exchanger.

INDICATION FOR USE:

The Apex HP M Adult Hollow Fiber Membrane Oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

TECHNOLOGICAL CHARACTERISTICS:

The Apex HP M Adult Hollow Fiber Membrane Oxygenator is identical in design, materials, operating principles and control mechanisms to the Apex HP M Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator, unmodified device. The changes consist of: the lack of the coating material on the blood contact surfaces, a general reviewing of the labeling, and the updating of the labeling as a consequence of these minor modifications. The fundamental scientific technology is unchanged. The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1:1997 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials. No new materials are used in the APEX HP M oxygenator compared to the unmodified device except the lack of the coating material, as a result of the modifications. Therefore, this 510(k) cross references biocompatibility data for the APEX M predicate device (#K014080). Tests were performed on devices accelerated aged to an equivalent of three years real time aging. Sterility, pyrogenicity, EO residuals and package integrity testing were also conducted. The results of testing met established specifications.

Similarly, the package integrity testing has not been performed since the packaging is unchanged from unmodified device. For this reason this 510(k) cross references packaging data previously submitted for the unmodified device (#K083021).

IN VITRO TEST RESULTS:

The functional parameters exhibited by APEX HP M Ph.I.S.I.O. apply also to APEX HP M as no technical modifications were introduced into the device.

CONCLUSION:

Test results show that the APEX HP M performs in a manner substantially equivalent to the unmodified device. Biocompatibility studies demonstrate that the device is biocompatible according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that APEX HP M is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 19 2009

Sorin Group Italia S.R.L.
c/o Mr. Barry Sall
Principal Consultant
195 West Street
Waltham, MA 02451

Re: K092895
APEX HP M Adult Hollow Fiber Membrane Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Oxygenator Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: September 18, 2009
Received: September 21, 2009

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K092895

Device Name: APEX HP M Adult Hollow Fiber Membrane Oxygenator.

Indication for Use:

The APEX HP M Adult Hollow Fiber Membrane Oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092895